EXHIBIT K

Anterior colporrhaphy: A randomized trial of three surgical techniques

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OBJECTIVE: The purpose of this study was to compare outcomes after anterior colporrhaphy with the use of 3 different surgical techniques.
STUDY DESIGN: One hundred fourteen women with anterior vaginal prolapse were randomly assigned to undergo anterior repair by one of 3 techniques: standard, standard plus polyglactin 910 mesh, or ultralateral anterior colporrhaphy. Before and after operation, patients underwent physical examination staging of prolapse; the International Continence Society system was used. Symptoms were assessed by questionnaire and visual analog scales. We defined "cure" as satisfactory (stage I) or optimal (stage 0) outcome at points Aa and Ba.
RESULTS: Of 114 patients who were originally enrolled, 109 patients underwent operation, and 83 patients (76%) returned for follow-up. Mean age (± SD) was 64.7 ± 11.1 years. At entry, 7 patients (7%) had stage I anterior vaginal prolapse; 35 patients (37%) had stage II anterior vaginal prolapse; 51 patients (54%) had stage III anterior vaginal prolapse; and 2 patients (2%) had stage IV anterior vaginal prolapse. At a median length of follow-up of 23.3 months, 10 of 33 patients (30%) who were randomly assigned to the standard anterior colporrhaphy group experienced satisfactory or optimal anatomic results, compared with 11 of 26 patients (42%) with standard plus mesh and with 11 of 24 patients (46%) with ultralateral anterior colporrhaphy. The severity of symptoms that were related to prolapse improved markedly (preoperative score, 6.9 ± 2.7; postoperative score, 1.1 ± 0.8). Twenty-three of 24 patients (96%) no longer required manual pressure to void after operation.
CONCLUSION: These 3 techniques of anterior colporrhaphy provided similar anatomic cure rates and symptom resolution for anterior vaginal prolapse repair. The addition of polyglactin 910 mesh did not improve the cure rate compared with standard anterior colporrhaphy. (Am J Obstet Gynecol 2001;185:1299-306.)

Key words: Anterior vaginal prolapse, cystocele, anterior colporrhaphy, polyglactin 910 mesh

Successful treatment of anterior vaginal prolapse remains one of the most challenging aspects of pelvic reconstructive surgery. Anterior colporrhaphy has been the standard surgical treatment for anterior vaginal prolapse, although there are few prospective studies in the literature that document its success or failure. Anterior vaginal prolapse may recur after standard anterior colporrhaphy in up to 40% of patients.[1,2] This high rate of recurrence has led to the addition of synthetic materials (such as absorbable or permanent synthetic mesh), with reported cure rates in uncontrolled studies of 93% to 100%.[3-5] However, permanent mesh may erode through the vagina in up to 25% of cases.[5] To our knowledge, there have been no controlled studies that examined outcomes after anterior vaginal prolapse repair with absorbable synthetic mesh.

The objective of our study was to compare outcomes after the random assignment of patients with anterior vaginal prolapse to one of 3 different techniques of anterior colporrhaphy: standard, standard plus polyglactin 910 mesh (Vicryl; Ethicon, Somerville, NJ), or ultralateral anterior colporrhaphy.

Material and methods

The Institutional Review Board at the Cleveland Clinic approved this research protocol; all of the patients provided written informed consent for participation. From June 1996 to May 1999, all patients who underwent operation for anterior vaginal prolapse were invited to participate. Patients were excluded if an antiincontinence procedure other than suburethral plication (ie, Burch colposuspension, sling, or needle suspension) was planned as part of their surgical

From the Departments of Gynecology and Obstetrics and Biostatistics and Epidemiology, Cleveland Clinic Foundation.
Supported by the American College of Obstetricians and Gynecologists/Ethicon Research Award for Innovations in Gynecologic Surgery, and by the Department of Gynecology and Obstetrics at the Cleveland Clinic Foundation.
Presented at the Twenty-seventh Annual Meeting of the Society of Gynecologic Surgeons, Orlando, Fla, March 5-7, 2001.
Reprints not available from author.

0002-9378/2001 $35.00 + 0 6/6/119081
doi:10.1067/mob.2001.119081

procedures. Other planned procedures for prolapse did not preclude study participation and did not affect group assignment.

All patients received preoperative antibiotic prophylaxis. To assure consistency, details of the surgical procedures were determined before study initiation by the 4 original participating surgeons. The administration of anesthesia and preparation of the surgical field were performed in the standard manner. A dilute solution of epinephrine (1:200,000) was used routinely for vaginal infiltration. Suburethral plication with No. 0 polydioxanone sutures (Ethicon, Somerville, NJ) was performed in the same manner in all groups. After the anterior vaginal prolapse repair was complete, the vaginal epithelium was trimmed and closed with a running locked stitch of 2-0 polyglactin 910 (Vicryl). Other procedures were performed as necessary before or after anterior vaginal prolapse repair.

There were 3 study groups. One group was designated "standard anterior colporrhaphy." An anterior vaginal incision was made in the midline, and dissection was performed to separate the vaginal epithelium from the underlying muscularis. After the suburethral plication, the muscularis was plicated without tension in the midline with interrupted stitches of No. 0 polydioxanone sutures. The second group was designated "ultralateral anterior colporrhaphy." After a midline anterior vaginal incision was made, dissection was performed laterally to the limits of the pubic rami on each side. After the suburethral plication, the paravaginal connective tissue was plicated under tension in the midline with interrupted stitches of No. 0 polydioxanone sutures. The third group was designated "standard anterior colporrhaphy plus mesh." In this group, the procedure for standard anterior colporrhaphy was performed. After midline plication of the vaginal muscularis, a piece of polyglactin 910 mesh (Vicryl) was cut to fit the space over the plication. The mesh was anchored at the lateral limits of the dissection with interrupted stitches of 2-0 Vicryl, and the vaginal epithelium was closed over the mesh.

One hundred fourteen patients were randomly assigned to one of the 3 surgical techniques for anterior vaginal prolapse. The unit of randomization was individual. The allocation schedule was a computer-generated random numbers table. Group assignment was concealed in sealed opaque envelopes until randomization at the time operation was scheduled. It was not possible to blind surgeons or patients to group assignment. Surgeons were informed of each subject's group assignment on the day before operation.

Patients completed questionnaires about urinary symptoms and sexual function and underwent physical examination before and after operation at about 6 months, 1 year, and 2 years. All patients were examined before and after operation by a research nurse who was experienced in the use of the pelvic organ quantification staging system approved by the International Continence Society.[6] The nurse was unaware of the subject's group assignment. Examinations were performed with Sims' speculums with the patients in the lithotomy position in stirrups on a standard gynecologic examining table. The maximal extent of prolapse was measured with Valsalva maneuver or cough and confirmed by the patient as the most protrusion she experienced. Methods, definitions, and descriptions conform to the standards recommended by the International Continence Society, except where specifically noted.[6]

Continuous variables were presented as mean ± SD; ordinal variables were presented as median with interquartile ranges. Symptoms were considered present for all questionnaire responses except "never or rarely." Severity of symptoms was assessed with a visual analog scale that ranged from 1 to 10 and was analyzed as a continuous variable. Numbers do not always equal the total sample size because of missing data. Stage of prolapse was defined at point Aa (midline anterior vagina 3 cm proximal to the external urethral meatus), point Ba (the most dependent position of the anterior vagina), and the most advanced prolapse at any vaginal site. Centimeter measures of vaginal position and stage of prolapse were analyzed as ordinal variables. Surgical outcome of anterior vaginal prolapse repair was defined as optimal when both points Aa and Ba were at stage 0 (−3 cm). Outcome was satisfactory when both points Aa and Ba were at stage I (−2 cm) and improved from preoperative staging. *Cure* was defined as optimal or satisfactory anatomic outcome. Outcome was unsatisfactory (failure) when either point Aa or Ba was at stage II or worse (−1 cm or lower) or unchanged or worse from preoperative staging. These definitions conform to recommendations from the National Institutes of Health Terminology Workshop for Researchers in Female Pelvic Floor Disorders.[7]

The study was designed to detect absolute differences of 30% or more among groups on the proportion of women in whom satisfactory or optimal results were achieved. To ensure power of at least 80% and to limit the chance of type I error to 5%, the number of patients per group was estimated to be 31. We added approximately 15% to this to allow for loss to follow-up to arrive at the final sample size of 114 patients.

Group comparisons of baseline and demographic characteristics were made with chi-square or Fisher exact tests for categoric factors; *t* tests or rank sum tests were used for continuous factors, as appropriate. Because of differences in follow-up time in the primary outcome measure, we used the Kaplan-Meier method to estimate the proportion of successes at follow-up and the log-rank test for comparing success rates. Preoperative-to-postoperative changes in symptoms were classified as resolved, persistent, or new onset from baseline to most recent follow-up

Table I. Demographic and clinical characteristics of 109 patients overall and by surgical group

Charactistic	*Overall (n = 109)*	*Group 1* (n = 39)*	*Group 2† (n = 35)*	*Group 3‡ (n = 35)*
Age (y)§	64.7 ± 11.1	65.6 ± 11.2	62.4 ± 13.3	66.0 ± 11.2
Menopausal status				
Premenopausal	14 (13%)	4 (10%)	7 (20%)	3 (9%)
Postmenopausal				
With estrogen	49 (44%)	15 (40%)	13 (37%)	19 (56%)
Without estrogen	48 (43%)	19 (50%)	15 (43%)	12 (35%)
Hysterectomy	49 (46%)	19 (50%)	16 (46%)	14 (41%)
Previous prolapse/incontinence operation	9 (8%)	4 (10%)	2 (6%)	3 (9%)
Stage of prolapse at point Aa				
Stage 0	2 (2%)	2 (6%)	0	0
Stage I	7 (7%)	4 (11%)	1 (3%)	2 (6%)
Stage II	41 (43%)	13 (37%)	13 (45%)	15 (48%)
Stage III	45 (47%)	16 (46%)	15 (52%)	14 (45%)
Stage of prolapse at point Ba ¶				
Stage 0	0	0	0	0
Stage I	7 (7%)	3 (9%)	2 (7%)	2 (6%)
Stage II	35 (37%)	12 (34%)	10 (34%)	13 (42%)
Stage III	51 (54%)	19 (54%)	16 (55%)	16 (52%)
Stage IV	2 (2%)	1 (3%)	1 (3%)	0

Note: There were no statistically significant differences among the 3 surgical groups.
*Standard anterior colporrhaphy.
†Ultralateral anterior colporrhaphy.
‡Standard anterior colporrhaphy with mesh.
§Mean ± SD.
‖Midline anterior vagina 3 cm proximal to the external urethral meatus.
¶Most dependent portion of the anterior vagina.

and tested for significant within-subject change with the use of McNemar's test. Sign tests were used to assess the statistical significance of improvements within surgical groups, and Kruskal-Wallis tests were used for comparisons between groups.

Results

Fig 1 shows the stages of the trial, with patient follow-up. Of the 114 patients who were randomized originally, 4 patients did not undergo operation (preoperative atrial fibrillation, 1 patient; insurance reasons, 1 patient; and unknown reasons, 2 patients), and 1 patient did not undergo anterior colporrhaphy at the time of prolapse operation; these 5 patients were excluded from all analyses. Five patients did not undergo the procedure as allocated (Fig 1). All patients in the standard anterior colporrhaphy group underwent operation as assigned; 4 patients in the ultralateral anterior colporrhaphy group did not undergo operation as assigned (standard procedure, 3 patients; standard anterior colporrhaphy with mesh, 1 patient); and 1 subject in the standard with mesh group underwent standard anterior colporrhaphy. For the analysis of the primary outcome of anatomic success, patients were analyzed in the group to which they had been randomly assigned (intention to treat analysis). There was no significant difference among the 3 groups ($P = .578$). All subsequent results that were reported were based on the actual operations that were performed.

Three patients died after operation, 2 patients with no follow-up (both in the anterior colporrhaphy with mesh group) and 1 patient with follow-up at 6 months (standard anterior colporrhaphy group). A 76-year-old woman died of a myocardial infarction 3 months after operation; a 69-year-old woman died of pancreatic cancer 1 year after operation; and a 79-year-old woman died of unknown causes 1 year after operation. Twenty-six patients did not return for follow-up after operation: 2 patients were in the standard anterior colporrhaphy group; 9 patients were in the anterior colporrhaphy with mesh group, and 15 patients were in the ultralateral anterior colporrhaphy group. Patients in the ultralateral anterior colporrhaphy group were significantly less likely to complete follow-up compared with the other 2 groups ($P = .0007$).

Table I shows the demographic and clinical characteristics of the 109 patients who underwent operation. There were no statistically significant differences between patients in the 3 study groups. In addition to anterior vaginal prolapse repair, other procedures that were performed included vaginal hysterectomy (n = 57 procedures; 53%), posterior colporrhaphy (n = 101 procedures; 94%), enterocele repair (n = 28 procedures; 26%), and vaginal vault suspension (n = 48 procedures; 44%). Mean hospital length of stay was 2.1 ± 0.5 days. Most patients (n = 100 patients; 93%) underwent postoperative bladder drainage with suprapubic catheters for a mean time of 20.4 ± 18.5 days; there was no differ-

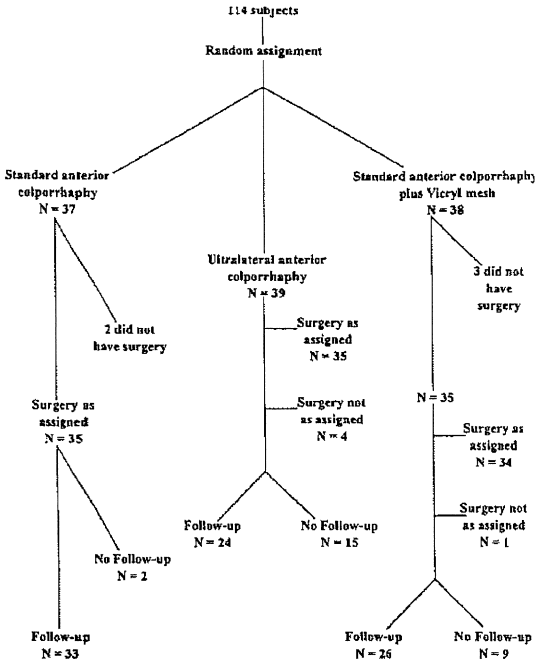

Fig 1. The randomized trial profile, including total sample size, group assignments, the number of patients who did not receive treatment as allocated, and losses to follow-up.

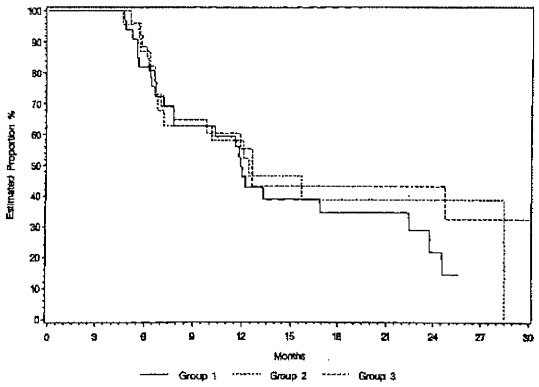

Fig 2. Comparison of the 3 study groups in outcome after anterior vaginal prolapse repair with the use of the Kaplan-Meier statistic. There was no significant difference in proportion of patients with satisfactory or optimal outcome at median follow-up of 23.3 months. *Group 1*, Standard anterior colporrhaphy; *Group 2*, ultralateral anterior colporrhaphy; *Group 3*, standard anterior colporrhaphy plus mesh.

ence in the duration of catheter use by the study group ($P = .70$). One patient experienced postoperative hemorrhage that required transfusion (standard anterior colporrhaphy group), and 1 patient had a pulmonary embolism (ultralateral anterior colporrhaphy group). There were no other major postoperative complications. One subject experienced mesh erosion, which was treated by excision of the exposed mesh in the office with subsequent healing of the vagina. There were no other complications because of the mesh.

Eighty-three patients returned for at least 1 follow-up visit, with a median follow-up time of 23.3 months (range, 4.5-44.4 months). Ten of 33 patients (30%) in the standard anterior colporrhaphy group had satisfactory or optimal anatomic results, compared with 11 of 26 patients (42%) in the standard plus mesh group and 11 of 24 patients (46%) in the ultralateral anterior colporrhaphy group. As shown in Fig 2, there was no difference among the 3 groups in the proportion of patients with optimal or satisfactory anatomic outcome at points Aa and Ba.

Table II shows symptoms before and after operation in the 83 patients who returned for follow-up. There were no differences among the study groups (data not shown). The severity of prolapse symptoms showed a marked improvement, with a mean change of 5.7 ± 2.8 points on the visual analog scale. The severity of urinary symptoms improved to a lesser degree, with a mean change of 2.5 ± 3.9 points. Symptoms that were related to sexual function also improved, with a mean change of 2.4 ± 3.9 points.

Comment

This prospective randomized study sought to determine whether there was a difference in the rate of cure of anterior vaginal prolapse among 3 different surgical techniques of anterior colporrhaphy. Anterior colporrhaphy corrects anterior vaginal wall prolapse by plicating the layers of vaginal muscularis and adventitia overlying the bladder or by plicating paravaginal tissue in such a way as to reduce the protrusion of the bladder and anterior vagina. Modifications of the technique depend on how lateral the dissection is carried, where the plicating sutures are placed, and whether additional layers (natural or synthetic) are placed in the anterior vagina for extra support. We found that there was no difference in the rate of anatomic correction or in symptomatic response among the 3 different techniques of anterior colporrhaphy that were used in this study: traditional plication, traditional plication plus Vicryl mesh, or plication under tension with lateral suture placement. For the surgeon, little advantage seems to be gained by placing absorbable mesh over a traditional anterior colporrhaphy. Surprisingly, the exact placement of sutures (traditional vs ultralateral) does not lead to substantial differences in outcome.

To our knowledge, this is the only randomized clinical trial that compared different surgical techniques of anterior colporrhaphy for the primary purpose of prolapse re-

Table II. Symptoms before and after operation in 83 patients with follow-up

Symptoms	
Severity of prolapse symptoms*	
Preoperative	6.9 ± 2.7
Postoperative	1.1 ± 0.8
Urinary urgency (n)	
Preoperative	43/82 (52%)
Postoperative	33/82 (40%)
Resolved	19/42 (45%)
Persistent	23/42 (55%)
New onset	10/39 (26%)
Urge incontinence (n)	
Preoperative	33/82 (40%)
Postoperative	21/82 (26%)
Resolved	18/32 (56%)
Persistent	14/32 (44%)
New onset	7/49 (14%)
Stress incontinence (n)	
Preoperative	15/82 (18%)
Postoperative	9/82 (11%)
Resolved	11/15 (73%)
Persistent	4/15 (27%)
New onset	5/66 (8%)
Manual pressure for voiding (n)	
Preoperative	24/82 (29%)
Postoperative	2/82 (2%)
Resolved	23/24 (96%)
Persistent	1/24 (4%)
New onset	1/57 (2%)
Severity of urinary symptoms*	
Preoperative	5.0 ± 3.3
Postoperative	2.5 ± 2.3
Sexually active (n)	
Preoperative	33/81 (41%)
Postoperative	31/82 (38%)
Dyspareunia (n)	
Preoperative	6/27 (30%)
Postoperative	4/27 (22%)
Resolved	3/6 (50%)
Persistent	3/6 (50%)
New onset	1/21 (5%)
Severity of symptoms related to sexual function*	
Preoperative	4.5 ± 3.3
Postoperative	2.0 ± 2.3

Preoperative and postoperative proportions are based on the total sample of 83 patients. Proportions of patients with resolution and persistence of symptoms are calculated with the denominator of patients with that symptom present before operation. Proportions of patients with new onset of symptoms are calculated with the denominator of patients without that symptom before operation. Proportions do not always equal 100% because of missing data.

*Mean ± SD of visual analog scale (range, 1-10).

pair. (All other randomized trials of anterior colporrhaphy have focused on the treatment of stress incontinence.[8]) In addition to providing comparative information, our study provides useful information on the surgical cure rate of anterior vaginal prolapse and on symptom response for this technique. Anterior colporrhaphy appears to provide excellent relief of symptoms that are related to vaginal protrusion. It does not appear to adversely affect sexual function and may even be associated with improvement. Although there was significant voiding dysfunction in the early postoperative period, prolonged voiding dysfunction did not occur in these patients. The patients accepted for this study did not have significant stress incontinence at entry; therefore, no conclusions can be drawn from this study about the correction of genuine stress incontinence with anterior colporrhaphy plus suburethral plication. Previous studies have shown relatively poor cure rates compared with other bladder suspension techniques for the treatment of stress incontinence.[8]

We found that anterior colporrhaphy in many cases leaves the anterior vaginal wall about at the level of the hymen, which is stage II when judged by the International Continence Society prolapse staging criteria.[6] By the definitions of cure and failure set before data analysis, our study considered this a surgical failure. However, the low rate of symptoms in these patients shows that many patients are satisfied with their surgical results. Defining *cure* as point Aa of the anterior vaginal wall 2 or 3 cm above the hymen might be difficult for this surgical technique to achieve. As opposed to a colposuspension procedure in which the anterior vaginal wall and bladder neck are pulled retropubicly, the anterior colporrhaphy attempts to support the urethra and bladder neck by bringing vaginal muscularis and periurethral endopelvic fascia together below the urethra and bladder. This creates a suburethral shelf of tissue between the anterior vaginal wall epithelium and the urethra. Thus, although the urethra and bladder neck may be elevated somewhat and immobile, the anterior vaginal wall does not appear elevated much above the hymen. It is possible that strict definitions of anterior vaginal wall measurements may be poor predictors of "success" with this particular operation.

Repair of anterior vaginal prolapse is still acknowledged as one of the most challenging aspects of pelvic reconstructive operation in terms of the achievement of a durable result. Despite this, there are few reports in the literature on outcomes after anterior vaginal prolapse repair. Variations on anterior colporrhaphy have been reported with excellent success rates (96% in one series of anterior colporrhaphy and needle suspension)[9] that have not been reproduced by others (41%-66% success).[10,11] Paravaginal repair (restoration of anterior vaginal support at the level of the arcus tendineus fascia pelvis) would seem to provide a closer approximation of "normal" support, and initial reports of its success seem encouraging.[12] However, technical difficulty with the vaginal approach to paravaginal repair has limited its widespread use in clinical practice. There are no studies that compare paravaginal repair (vaginal or retropubic approach) with anterior colporrhaphy.

The limitations of our study should be acknowledged. Small differences in cure rate would not necessarily be detected by our study, with the possibility of

type II error because of small sample size. However, small differences in cure rate are probably not clinically significant and would not change our overall conclusions. Five surgeons contributed patients to our study. Although we agreed to standardized surgical procedures before the study started, it is possible that there were variations in technique by surgeon. However, this more closely represents expected outcomes in actual clinical practice, compared with a trial with only one surgeon performing the procedures. Loss to follow-up occurred in a higher proportion of patients than our original estimate. If all patients who were lost to follow-up were counted as "cures," the estimated cure rate would increase to 53% for all study groups combined (compared with 38% in the patients who completed follow-up); if patients who were lost to follow-up were counted as "failures," the estimated cure rate would decrease to 21% overall.

We conclude that there does not appear to be an advantage of one suturing technique over another for anterior colporrhaphy, and that the addition of absorbable mesh to traditional anterior colporrhaphy does not substantially improve cure rates. Although the rate of elevation of the anterior vaginal wall above stage II is relatively low, we found a high rate of symptomatic improvement in our patients. Further work is needed to define the best surgical techniques and the best outcome measures for different reconstructive surgical procedures for anterior vaginal prolapse.

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Discussion

Dr Douglass Hale, Indianapolis, Ind. The authors are to be congratulated for carrying out the first randomized study of anterior colporrhaphy for the treatment of anterior vaginal wall prolapse. Gynecologists should find it startling that only now has such a study been completed, because anterior colporrhaphy is one of the most frequently performed operations in gynecologic surgery. The National Hospital Discharge Survey reports 166,000 anterior and posterior repairs performed as primary procedures in their last yearly report.[1] This number underestimates the actual number because this report is limited to listing only primary procedures. Despite the number of anterior colporrhaphies performed each year, no controlled scientific data of long-term outcome for prolapse exist. In fact, most studies of anterior colporrhaphy are in reference to the treatment of genuine stress incontinence.[2] Dr Weber and her colleagues have undertaken a needed and difficult study; for this, they should be recognized.

The term *colporrhaphy* has its roots in the words *elytrorhaphie* and *kolporaphy* that date back to the early 19th century. At this time, anything that caused a scarring of the vaginal walls to reduce prolapse was included in this term.[3] The surgical technique has changed little for the last 100 years.[4] Semantic debates over the actual tissue being plicated date back to the 19th century. The names Cuneo, Sears, Ricci, Uhlenhuth, among many others, provide the protagonists or antagonists in this drama.[5-8] Dr Weber and her colleagues previously addressed this issue, which was confirmed by Dr Farrell at the 2000 American Urogynecologic Society Annual Scientific Meeting who concluded that the tissue being plicated is vaginal muscularis, not a true fascial layer.[9,10]

The purpose of the study was to compare 3 different techniques of anterior repair with the use of outcome measures of anatomic cure and symptom improvement. After a power analysis was performed and the number of patients required for each arm was determined, 114 patients were randomized; 83 patients (76%) had a median follow-up of 23.3 months. An independent observer performed the follow-up examinations and compared postoperative and preoperative symptom questionnaires.

The authors conclude that there is no difference in the 3 techniques for anatomic cure and symptom resolution. They also state that this study "provides useful information on surgical cure rate of anterior vaginal prolapse and on symptom response for this technique. Anterior colporrhaphy appears to provide excellent relief of symptoms related to vaginal protrusion."

A major criticism of this study is the inability to control for the other prolapse procedures that were performed in these patients, making it difficult to draw any sound conclusions regarding the effects of anterior colporrhaphy alone. Additional procedures represent confounding variables for both anatomic cure and symptom response to an anterior repair. Although not directly stated, it appears that no patient in this study underwent anterior repair alone. Fifty-three percent of the patients underwent vaginal hysterectomy; 94% of the patients underwent posterior repair; 26% of the patients underwent enterocele repair, and 44% of the patients underwent vaginal vault suspension. The authors can conclude that their prolapse operation as a whole had the reported anatomic and symptom outcomes, but they cannot attribute these results to only the anterior repair. Procedures to support the cuff may have a great impact on the anatomic position of Aa and Ba. Total vaginal hysterectomy for a prolapsed uterus may have more to do with symptom improvement in these patients than anterior colporrhaphy. The authors could have come up with similar conclusions about symptom outcomes had they instead chosen to look at the patients who underwent posterior colporrhaphy. The combination of multiple operations needs further discussion and must be recognized as a serious limitation to the conclusions that can be drawn.

In addition to these comments, I pose the following questions:

1. Although for a surgical outcome study the follow-up was quite good (76%), the authors did not achieve the required number of 31 patients in each group. Therefore, they cannot accept the null hypothesis that there is no difference in outcome among the groups. In the "Comment" section, the inadequate sample size is addressed by stating that "small differences" in cure would not be detected but that these differences are "probably not clinically significant." However, they were looking for the fairly large difference of 30% between the groups. This would make achieving the target numbers even more important so that a type II error did not occur. The power of this study is far below 80%, with only 24 patients available for follow-up in the ultralateral group.
2. No mention is made of statistical significance with regard to the questionnaire data. Were any of these data statistically significant?
3. Would the authors agree that, ideally, the most effective way to eliminate patient symptoms because of prolapse is to restore normal anatomy? If this is the case, an anterior repair could actually exaggerate a paravaginal cystocele and possibly explain the high (62%) anatomic failure rate. Could the authors describe where they picture the "shelf" that is created as being anchored laterally? Should it not be supported laterally by an intact attachment to the arcus tendineus fascia pelvis? If it were, why would one of their repairs not be expected to lift the anterior wall into its correct position? Can we assume the patients were not at the level of the hymen when they left the operating room? If not, why would the support of the "shelf" change over time, if not for mechanical failure of the tissue? Would this not be expected to continue to worsen with time?
4. Ninety-four percent of patients also underwent a posterior colporrhaphy. The literature reports a 15% to 30% rate of dyspareunia after this procedure.[11,12] Can the authors comment on what they do differently that results in improvement over the previously reported rates? This points out the difficulty of trying to report the effects of a single procedure when multiple procedures were performed.
5. What do the authors think of the perineal nerve damage that is associated with anterior wall dissection that has been described in at least 3 papers?[13-15]
6. Have the results of this study, with a 62% anatomic failure rate, changed the authors' approach to anterior wall prolapse?

Once again, the authors are to be congratulated on this study and all the work that went into it. Surgical studies such as these are time-consuming and frustrating to perform. The confounding variables significantly impact the study conclusions. Nonetheless, this paper will add to the limited data available on anterior colporrhaphy for the treatment of anterior wall prolapse. Conclusions from symptoms should not be overstated.

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Dr Weber (Closing). The best we can do is the statistical analysis after the study is completed. We examined the performance of other procedures for any effect on our primary outcome or any of the secondary outcomes, and there was none. This is one of the difficulties that we face in designing a surgical trial. We have patients who have a combination of problems, but we want to select one of their particular problems to focus on for the study, so we have to accept the possibility of confounding and do the best that we can in the analysis after the study is completed. As far as the sample size question and accepting or rejecting the null hypothesis, we did the best we could in setting up the study to give us what we thought was a generous amount of extra for loss to follow-up; it happened that our follow-up was higher than our projected 15%. I think that we came close to our projected sample size to detect the difference of 30%; as you observed, none of the differences approached 30%, so it would not have been possible even with a few extra patients to have detected a difference that was statistically significant. What we are really looking for is clinical significance. We are happy to know about statistical significance, whether the effects we see are due to chance or not. But what we really want to know is whether the differences we detect are clinically important. I think we saw no clinically important differences here. In regards to the question about the symptom questionnaires, all of the improvements and symptoms were highly statistically significant. There was no difference in the improvement among the 3 groups, but as a whole, women improved substantially from before to after operation. I recognize the point that is a global question about their prolapse symptoms, and we were focusing on their anterior repair, but again that is just one of the limitations of studies such as this. The patient cannot possibly tell you what part of her prolapse is bothering her more, so you just have to go with the global question to get an idea of what about her prolapse is bothering her overall. "Are we doing anything differently?" No, not at this point. We were hoping with our study to find that one procedure was better than the others, and then we could have changed to the use of that procedure exclusively. Because that is not what we found, we have not really made a change in how we treat patients. I think anterior repair still has a place in the treatment of patients with anterior vaginal prolapse. As Dr Hale mentioned in the beginning of his comments, we have no other comparative studies to tell us whether other procedures are better or not. I would encourage all of you to start this process. It is a long process, but we have to start somewhere. We have to go home, design randomized trials, and carry them out.